DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

Crospon, Ltd.
% Paul E. Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K132337
Trade/Device Name: EsoFLIP® Balloon Dilation Catheter
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PID, PIE
Dated (Date on orig SE ltr): August 8, 2013
Received (Date on orig SE ltr): August 9, 2013

Dear Paul E. Dryden,

This letter corrects our substantially equivalent letter of October 7, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K132337

Device Name: EsoFLIP® Balloon Dilation Catheter

Indications for Use:

The EsoFLIP® Balloon Dilation Catheter is indicated for use in a clinical setting for dilating the gastro-esophageal junction of a patient with Achalasia.

Prescription Use XX (Part 21 CFR 801 Subpart D) or **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2013.10.07 16:43:01 -04'00'

510(k) Summary
Page 1 of 6

Date Prepared	25-Jul-13
Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland Tel – 011 [353] (91) 519882 Fax – 011 [353] (91) 519873
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EsoFLIP® Balloon Dilation Catheter ES-330
Common/Usual Name:	Esophageal Dilator
Classification / CFR:	KNQ / CFR 876.5365 / Class 2
Device:	EsoFLIP® Balloon Dilation Catheter
Predicate Devices:	K900924 - Cook Endoscopy Achalasia Balloon K120997 – Crospon – EndoFLIP® Catheter

OCT 07 2013

Device Description:
The EsoFLIP® balloon dilation catheter is a modification of the predicate Crospon EndoFLIP® catheters. The EsoFLIP® is a small catheter with an inflatable balloon which is inserted into the gastro-esophageal junction of a patient with Achalasia. It is connected to the EndoFLIP® controller system (K120997) and the catheter is attached to a syringe, pre-filled with a diluted saline solution, which is inserted into the syringe pump on the front of the EndoFLIP® system. The EsoFLIP® catheter is inserted by the clinician. The proposed balloon dilation catheter, EsoFLIP®, can also make diameter measurements electrically using the same impedance planimetry measuring technique as that deployed in the predicate EndoFLIP® system, K120997.

Modifications of these devices vs. Predicates:
The following is a summary of the differences between the proposed EsoFLIP® and the predicate Crospon EndoFLIP® catheters.

(1) Change in indications for use
(2) Change of the balloon material to a stiffer material, a material which is used in the predicate
(3) Increase the overall diameter of the balloon from 25 mm to 30 mm
(4) Reduce the number of Dest measurements points from 16 to 14
(5) Change of the tip to be a guidewire tip made from the same material in the predicate EndoFLIP®

510(k) Summary
Page 2 of 6
25-Jul-13

Indications for Use:
The EsoFLIP® catheter is indicated for use in a clinical setting for dilating the gastro-esophageal junction of a patient with Achalasia.

Patient Population: Patient population is patients with Achalasia.

Environment of Use: Hospitals and Surgery Centers

Contraindications:
- The EsoFLIP® System is contraindicated where endoscopy is contraindicated.
- Do not use the EsoFLIP® System on patients with actively-bleeding varices in the esophagus or with esophageal perforation.
- The EsoFLIP® catheter is not suitable for diameter measurements smaller than 8mm or greater than 30mm.

Predicate Device Comparison:

Table 1 compares the EsoFLIP® Balloon Dilation catheter to the predicate Cook Endoscopy Achalasia Balloon K900924.

The EsoFLIP® dilation catheter is viewed as substantially equivalent to the predicates Cook Endoscopy Achalasia Balloon K900924 and the EndoFLIP® system with catheter K120997 because:

Indications –
The dilation indications for use are identical to the Cook Endoscopy Achalasia Balloon K900924. This device is used to dilate strictures of the esophagus. [Specifically indicated for patients with Achalasia.]

Discussion – The indications for use are identical to the dilation predicate, Cook Endoscopy Achalasia Balloon, K900924.

Technology –
The EsoFLIP® Dest measurement technology, construction, and design is unchanged from the EndoFLIP® K120997 apart from a reduction in the measurement points from 16 to 14 and the increase in the balloon maximum diameter from 25 to 30mm.

The 30 mm maximum diameter and 80 mm dilation working length is identical to the Cook Endoscopy Achalasia Balloon, K900924.

The EsoFLIP® catheter features a guidewire tip (guidewire not supplied) while the Cook Endoscopy Achalasia Balloon K900924 is also used with a guidewire (guidewire not supplied; per the Cook IFU P/N 18931/0411).

510(k) Summary
Page 3 of 6
25-Jul-13

Discussion – The technology is unchanged from the Dest measurement predicate, EndoFLIP® - K120997.

The dilation technology of the EsoFLIP® catheter: maximum diameter and balloon working length, together with its use with a guidewire, is identical to the dilation predicate Cook Endoscopy Achalasia Balloon, K900924.

Environment of Use –
The environments of use - hospital and surgery centers – are identical to the predicates.

Discussion – The environments of use are unchanged and identical to the predicates, Crospon EndoFLIP® (K120997) and Cook Endoscopy Achalasia Balloon (K900924).

Patient Population –
The patient populations are identical, specifically indicated for patients with Achalasia.

Discussion – The patient population is unchanged and identical to the predicate Cook Endoscopy Achalasia Balloon (K900924).

Non-clinical Testing Summary -

Bench Testing –
We performed testing which included -

- DHF_1343 EsoFLIP Dilation Catheter DV Summary Test Report
- DHF_1290 EsoFLIP Balloon Manufacturer Cert of Conformance
- DHF_1296 EsoFLIP Dilation Catheter Bonds Test Report
- DHF_1300 EsoFLIP Balloon Fatigue Test Report
- DHF_1307 EsoFLIP Dest Performance Test Report
- DHF_1338 EsoFLIP Catheter Torque Tests - Test Report
- DHF_1340 EsoFLIP Balloon Compliance Tests - Test Report
- DHF_1342 EsoFLIP Catheter Assembly Tests - Test Report

The results demonstrate that the EsoFLIP® has met the performance specifications.

Materials –
The patient contacting materials in the EsoFLIP® catheter are identical to the predicate EndoFLIP® catheters, K120997.

In accordance with G95-1 and ISO 10993-1 the catheters are considered as

- Surface Contacting
- Mucosal membrane
- Limited duration (<24h)

They are single patient use, disposables. The materials are identical to the predicate EndoFLIP® catheters, K120997.

510(k) Summary
Page 4 of 6
25-Jul-13

Table 1 – Comparison of Proposed Device vs. Predicate

	EndoFLIP® system with catheter K120997	Cook Endoscopy Achalasia Balloon K900924	Proposed EsoFLIP® Catheter
Indications for Use	The EndoFLIP® system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity. Note: EndoFLIP® is a measurement system. It is not intended to perform a diagnostic test.	This device is used to dilate strictures of the esophagus. [Specifically indicated for patients with Achalasia.]	The EsoFLIP® catheter is indicated for use in a clinical setting for dilating the gastro-esophageal junction of a patient with Achalasia.
Environments of use	Hospital and surgery centers	Hospital and surgery centers	Hospital and surgery centers
Patient Population	Patients with esophageal disorders	Patients with Achalasia	Patients with Achalasia (Identical to K900924)
Contraindications	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.	Those specific to Upper GI Endoscopy. Those specific to dilation include but are not limited to: uncooperative patient, asymptomatic rings or strictures, inability to advance the balloon through the strictured area, coagulopathy, known or suspect perforation, severe inflammation or scarring near the dilation site.	The EsoFLIP® catheter is contraindicated where endoscopy is contraindicated. Do not use the EsoFLIP® System on patients with actively bleeding varices in the esophagus or with esophageal perforation. The EsoFLIP® catheter is not suitable for diameter measurements smaller than 8mm or greater than 30mm.

510(k) Summary
Page 5 of 6
25-Jul-13

	EndoFLIP® system with catheter K120997	Cook Endoscopy Achalasia Balloon K900924	Proposed EsoFLIP® Catheter
Prescription/OTC	Prescription use	Prescription use	Prescription use
Principle of Operation	Measurement: Provides an Estimated Diameter (D_{est}) of the balloon at 16 points along its length when inflated with saline solution. Dilation: Not indicated for dilation.	Measurement: No measurements. Dilation: Balloon inflates to 30mm diameter along a working length of 80mm.	Measurement: Provides an Estimated Diameter (Dest) of the balloon at 14 points along its length when inflated with saline solution. Dilation: Balloon inflates to 30mm diameter along a working length of 80mm (Identical to K900924).
Biocompatibility	All materials have passed biocompatibility tests in accordance with ISO 10993-1 (K120997)	Not disclosed	Identical materials to predicate Crospon EndoFLIP® catheter (K120997)
Compatibility With The Environment And Other Devices	Only operates with EndoFLIP® system	Not disclosed.	Only operates with EndoFLIP® system
Sterility	Accessories are supplied non-sterile, and are single patient use, disposable	Accessories are supplied non-sterile, and are single patient use, disposable	Accessories are supplied non-sterile, and are single patient use, disposable
Performance	Range: 5 to 25 mm Resolution: 0.1 mm Accuracy: ± 1mm (at 95% confidence) rounded to nearest integer	Product Number G24893 = 30 mm Accuracy: Not disclosed	Range: 8 to 30 mm Resolution: 0.1 mm. (Identical to K120997) Accuracy: ± 1mm (at 95% confidence) rounded to nearest integer. (Identical to K120997)

510(k) Summary
Page 6 of 6
25-Jul-13

Substantial Equivalence Conclusion :

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.